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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/524,666	03/13/2000	John G. Aceti	SMI-13459pA	6745

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EXAMINER

DABNEY, PHYLESHA LARVINIA

ART UNIT	PAPER NUMBER
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2643

24

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/524,666

Applicant(s)

ACETI ET AL.

Examiner

Phylesha L Dabney

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/29/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 23,24,40,43,45,49 and 55-57 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48 and 50-54 is/are allowed.
- 6) ☐ Claim(s) 1-22,25-39,41,42,44,46-47, and 58-63 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

This action is in response to the amendments submitted on 4 February 2003 and 24 October 2003 in which claims 1-22, 25-39, 41-42, 44, 46-54, 58-63 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1, 8-10, and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to teach how the earmold can have a shorter useful life than the base unit, as in claims 1 and 22.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 8-10, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is "the useful life" or a "shorter useful life", what is the shorter useful life for the earmold, or what is the useful life of the base unit?

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by **Voroba** (U.S. Patent No. 4,870,688).

Regarding claims 11, 13, 15, and 17-19, Voroba discloses a modular hearing aid comprising: a base unit (99, 100), an earmold (30) comprising a compliant material and a retention mechanism (20,40,50,52), and a module (70; 90,101) comprising a shell (72) and electronics (70; 60, 90).

Regarding claims 12 and 14, Voroba discloses the earmold comprises a battery (80) removable attached to the earmold.

Regarding claim 16, Voroba discloses the module (90, 101) comprises a microphone (90).

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4. Claims 44 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by **Youest et al** (U.S. Patent No. 6,097,825).

Regarding claims 44 and 47, Youest discloses a hearing aid comprising a base unit (50, 70, 90, 120) and a potting material (92a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Voroba et al** (U.S. Patent No. 4,870,688); or **Weeks** (U.S. Patent No. 5,748,743).

Regarding claim 1, as best understood with regard to the 112 1st and 2nd rejections above, Voroba or Weeks teaches a in the ear hearing aid comprising a base unit (99-100, Voroba; 1, Weeks), and an earmold (30; 10;) being able to be removably attached to the base unit comprising a compliant material. Neither Voroba nor Weeks specifically teaches the earmold having a shorter life than the base unit. However, it is known in the art to be able to replace the earmold portion within the life expectancy of the aid if the structure becomes compromised, i.e. brittle and torn, and improve comfort and hygienic concerns for the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to change

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the earmold of Voroba or Weeks within the life expectancy of the aid for improved comfort and hygienic concerns.

Regarding claim 8, the combination of Voroba or Weeks teaches the earmold forms an earmold tip (see figures).

Regarding claim 9, the combination of Voroba or Weeks teaches the earmold forms an earmold sleeve.

Regarding claim 10, the combination of Voroba or Weeks teaches the earmold forms an earmold tip and sleeve.

6. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Diethelm** (U.S. Patent No. 3,852,540), in view of **Voroba** et al (U.S. Patent No. 4,870,688).

Regarding claims 1-2, 6 and 8-10, as best understood with regard to the 112 1st and 2nd rejections above, Diethelm teaches a base unit (2), an earmold (1, 3) removable attached to the base unit, a retention mechanism (col. 3 lines 13-34), and the earmold comprising a battery (7, 8). Diethelm does not teach the type of material used for the earmold; however, it is known in the art, as evidenced by Voroba (30), to use soft, malleable, compliant material for the earmold to facilitate comfort to the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the shell of Diethelm from a soft, malleable, compliant material to facilitate comfort to the user. Neither Diethelm nor Voroba teaches the earmold having a shorter life than the base unit. However, it is known in the art to be able to replace the earmold portion within the life expectancy of the aid if the structure becomes compromised, i.e. brittle and torn, and improve comfort and hygienic concerns for the user.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to change the earmold of Diethelm in view of Voroba within the life expectancy of the aid for improved comfort and hygienic concerns.

Regarding claim 3, the combination of Diethelm and Voroba teaches a shell integrated with the earmold (1, 3) and housing the battery (8) and a receiver (5).

Regarding claim 4, the combination of Diethelm and Voroba teaches a base unit (2), an earmold (1, 3) removable attached to the base unit, a retention mechanism (col. 3 lines 13-34), and the earmold comprising a battery (7, 8) and receiver (5). Diethelm does not teach the type of material used for the earmold; however, it is known in the art, as evidenced by Voroba (30), to use soft, malleable, compliant material for the earmold to facilitate comfort to the user.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the shell of Diethelm from a soft, malleable, compliant material to facilitate comfort to the user.

Regarding claims 5 and 7, the combination of Diethelm and Voroba teaches a shell integrated with the earmold (1, 3) and housing the battery (8) and a receiver (5).

1. Claims 25, 31-35, and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Voroba** (U.S. Patent No. 4,870,688).

Regarding claims 25 and 31, Voroba teaches an earmold tip (Voroba, 30) comprising a vibration isolator portion (Voroba, 72) adapted for attachment within a hearing aid, having a receiver (Voroba, 70). Since Voroba excludes the receiver from having a diaphragm and the Examiner takes official notice that it is well known in the art for a receiver to have vibratory

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elements, i.e. diaphragms, for transmitting audible sound to the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a diaphragm within the receiver of Voroba to transmit audible sound.

Regarding claim 32, Voroba teaches the hearing aid includes a base unit (Voroba, 99-100) having a microphone Voroba, 90).

Regarding claims 33 and 34, refer to claims 25 and 32.

Regarding claim 35, Voroba teach using adhesive to secure the receiver to the earmold. However, the examiner takes official notice that it is extremely well known in the art to use adhesive for securely fixing the receiver to the earmold for limiting distorted audible sound. Therefore, it would have been obvious to one of ordinary skill in the art that to securely attach the receiver to the earmold to prevent distorted audible sound.

Regarding claims 58-60, see the rejection of claims 25-26.

7. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Voroba** et al (U.S. Patent No. 4,870,688); in view of **Schroder** (U.S. Patent No. 4,736,430).

Regarding claim 22, Voroba teaches replacing a base unit of a hearing aid comprising the steps: providing a modular hearing aid (10) having a base unit (200) an earmold (30) and a module component (70); releasing a securing mechanism (50, 52, 244, 246, 248); removing the base unit (200); discarding the base unit (col. 5, lines 23-52); placing a second base unit (col. 5 lines 23-27) onto the earmold; and attaching the securing mechanism (50, 52, 110, 112). Voroba does not teach the securing mechanism capable of being released by a user without the use of a separate tool or instrument. Schroder teaches an alternate rotational connection means (col. 2

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line 59 through col. 3 line 2) for securing two hearing aid modules together and making it easier to disconnect the two housings. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the rotational connection means in the invention of Voroba as taught by Schroder to make the two housings easier to separate.

However, it is known in the art to be able to replace the earmold portion within the life expectancy of the aid if the structure becomes compromised, i.e. brittle and torn, and improve comfort and hygienic concerns for the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to change the earmold of Voroba in view of Schroder within the life expectancy of the aid for improved comfort and hygienic concerns.

8. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Diethelm** (U.S. Patent No. 3,852,540), in view of **Voroba** (U.S. Patent No. 4,870,688), and further in view of **Baum** (U.S. Patent No. 2,487,038).

Regarding claims 20 and 21, Diethelm teaches a base unit (2), an earmold (1, 3) comprising a battery (7, 8) and receiver (5), and a retention mechanism (col. 3 lines 13-34). Diethelm does not teach the type of material used for the earmold; however, it is known in the art, as evidenced by Voroba (30), to use soft, malleable, compliant material for the earmold to facilitate comfort to the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the shell of Diethelm from a soft, malleable, compliant material to facilitate comfort to the user. Furthermore, the combination of Diethelm and Voroba does not teach the earmold having a flexible, mushroom shaped earmold tip.

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However, it is known in the art, as evidence by Baum (figs. 1-5), for an earmold tip to have horizontal flanges (Knudsen; 12) for tightly sealing the auditory canal to the outside, providing comfort to the user, and for simulating a mushroom shaped tip. Therefore, it would have been obvious to one of ordinary skill in the art to include the flange(s) onto the earmold (Diethelm; 1, 3) of the combination of Diethelm and Voroba for tightly sealing the auditory canal to the outside and providing comfort to the user.

9. Claims 25-30, 36-39, 41-42, and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Diethelm** (U.S. Patent No. 3,852,540), in view of **Baum** (U.S. Patent No. 2,487,038).

Regarding claims 25-27, Diethelm teaches an earmold tip (Diethelm (1, 3) comprising a vibration isolation portion (Diethelm, 1) adapted to attachment with in a hearing aid having a receiver (Diethelm, 5). Diethelm does not teach the earmold having a flexible, mushroom shaped earmold tip. However, it is known in the art, as evidence by Baum (figs. 1-5), for an earmold tip to have horizontal flanges (Baum; 11) for tightly sealing the auditory canal to the outside, providing comfort to the user, and for simulating a mushroom shaped tip. Therefore, it would have been obvious to one of ordinary skill in the art to include the flange(s) onto the earmold tip (Diethelm; 1, 3) for tightly sealing the auditory canal to the outside and providing comfort to the user.

Regarding claims 28, 30, and 38, the combination of Diethelm and Baum teaches the earmold tip comprising a sound bore (Diethelm; 6, 6a, 22, 23).

Regarding claim 29, the combination of Diethelm and Baum does not teach a spring surrounding the sound bore. However, the examiner takes official notice that it is known in the art to insert springs into earmold tips to increase stiffness and control navigation of the tip along the ear canal. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a spring in the invention of Diethelm and Baum to increase stiffness and control navigation.

Regarding claims 36, 39, 41, and 63, refer to claims 25, 26, and 28.

Regarding claim 37, refer to claim 29.

Regarding claims 42, claims 25, 27, 34, 35, 36, former claim 40, 41 cover the limitations of these claims.

Regarding claims 58-60, see the rejection of claims 25 and 26.

Regarding claim 61, see the rejection of claims 28, 30, 38 as they relate to claims 58.

Regarding claim 62, see the rejection of claims 4, 6, 11, 16, 20-21 as they relate to claims 58.

Allowable Subject Matter

10. Claims 46, 48 and 50-54 are allowed.

Response to Arguments

11. Applicant's arguments, see Paper Numbers 19-20, with respect to the rejection(s) of claim(s) 25 and 36 under 35 U.S.C. 103(a) have been fully considered and are persuasive.

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Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Diethelm and Baum (section 8).

With respect to claim 25, the rejection using the Diethelm reference has been newly rejected in section 8 above.

In response to applicant's argument that there is no suggestion to combine the Diethelm and Baum reference in the rejection of claim 36 (section 8 of office action), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Diethelm teaches the basic structure of the hearing aid including a microphone, battery, electronics, shell, and tip, etc. Diethelm fails to teach the specifics of the tip. In the similar field of canal inserted hearing apparatuses, Baum teaches a tip with horizontal flanges for sealing the auditory canal and providing comfort to the user through the flexibility of the Baum tip which is clearly shown in the curved representation of the tip (Baum, figure 2).

12. With respect to the applicant's arguments pertaining to claim 25 and the Voroba reference, Voroba teaches a flexible earmold tip (col. 7 lines 6-25) which satisfies the applicant's claim limitations since at least one of a multiple configurations of the applicant's earmold (12) has the ability to integrally form the earmold tip and sleeve (applicant's specification page 11 lines 7-8 and illustrated in figure 1).

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13. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., in-the-ear tip) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In addition, the examiner would like to point out that the reference completely-in-the-ear (CIC) and in-the-ear (ITE) have separate meaning in the hearing aid art. An ITE hearing aid does not necessarily have to be completely in the ear canal.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phylesha L Dabney whose telephone number is 703-306-5415. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, Fridays 8:30-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Curtis Kuntz can be reached on 703-305-4708. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-4700.

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 872-9314, for formal communications intended for entry and for informal or draft communications, please label "Proposed" or "Draft" when submitting an informal amendment.

(703) 306-0377, for customer service questions.

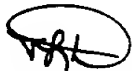
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Hand-delivered responses should be brought to Crystal Park II, 2121 Crystal Drive, Arlington, VA., Sixth Floor (Receptionist).

PLD



January 23, 2004



HUYEN LE
PRIMARY EXAMINER